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Summary

Acclaim™ Total Elbow System

510(k) SUMMARY

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46580
510(K) CONTACT:	Natalie S. Heck Manager, Regulatory Affairs DePuy Orthopaedics, Inc. PO Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
TRADE NAME:	Acclaim™ Total Elbow System
COMMON NAME:	Elbow Prosthesis
CLASSIFICATION:	When used as a semi-constrained (unlinked elbow), it is a Class II device per 21 CFR §888.3160 When used as a constrained (linked), it is a Class II device per 21 CFR §888.3150
DEVICE PRODUCT CODE:	87 JDB – Prosthesis, Elbow, Semi-Constrained, Cemented (Class II) 87 JDC – Prosthesis, Elbow, Constrained, Cemented (Class II)
SUBSTANTIALLY EQUIVALENT DEVICES:	Acclaim™ Total Elbow System – K992656 (formerly cleared as DePuy Total Elbow System) Mark II Elbow System – K872084

DEVICE DESCRIPTION:

C. <u>Indications for Use:</u>

The Acclaim™ Total Elbow System is indicated to reduce pain and improve the function and mobility of the affected joint in patients with a painful arthritic joint due to osteoarthritis, rheumatoid arthritis, or post traumatic arthritis and pathological fractures of the distal humerus in which adequate bone stock exists for the fixation of prosthetic components.

Total Elbow replacement may be considered for younger patients, if, in the opinion of the surgeon, an unequivocal indication for elbow replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and elbow joint loading can be assured. This included patients for whom an immediate gain of elbow

mobility may lead to an expectation of significant improvement in the quality of their lives.

The Acclaim™ Total Elbow System is intended for cemented use only.

D. Device Description:

The Acclaim™ Total Elbow System replacement hinge pin assembly is designed as a replacement of a linked (constrained) elbow hinge pin assembly due to hinge pin disassociation. When the Acclaim Total Elbow System is implanted as a linked system, it is held together with the linked ulnar component and pin assembly, and is used when there is poor bone stock.

The Acclaim™ Total Elbow System replacement hinge pin assembly is comprised of a polyethylene humeral yoke and locking sleeve, with a metal locking pin, ulnar bearing, ulnar bearing screw, washer, and wire. The replacement hinge pin assembly is used in conjunction with well-fixed humeral and ulnar components.

Acclaim™ Total Elbow System replacement hinge pin assembly design includes modifications to the ulnar bearing, polyethylene sleeve, and locking pin. In addition, a washer and cross-pin locking mechanism has been included to the assembly using the same design as the Mark II Total Elbow System locking mechanism, previously cleared in K872084 dated June 25, 1987.

E. Substantial Equivalence:

The substantial equivalence of the Acclaim™ Total Elbow System replacement hinge pin assembly is substantiated by its similarity in indications for use, design, materials, sterilization and packaging to the current Acclaim™ Total Elbow (formerly cleared as DePuy Total Elbow System, K992656), DePuy Mark II Elbow (K872084) hinge pin assemblies.

The determination of substantial equivalence for this device was based on a detailed device description, and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2006

DePuy Orthopaedics, Inc.
c/o Ms. Natalie S. Heck
Manager, Regulatory Affairs
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K060696
Trade/Device Name: Acclaim Total Elbow System
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Codes: JDC, JDB
Dated: March 15, 2006
Received: March 16, 2006

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

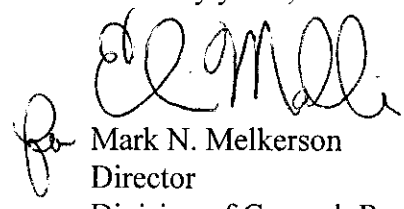
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060696
Device Name: Acclaim™ Total Elbow System

Indications for Use:

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The Acclaim™ Total Elbow System is intended for cemented use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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